



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,025	03/05/2007	Marianna Foldvari	58152-8001.US00	2769
22918	7590	08/17/2009		
PERKINS COIE LLP P.O. BOX 1208 SEATTLE, WA 98111-1208			EXAMINER NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			08/17/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

Claims 1-11 and 20-23 are pending in the present application, and they are subjected to the following restrictions.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11, drawn to a topical delivery system comprising a Gemini surfactant in admixture with a biological active agent.

Group II, claims 20-22, drawn to a method for treatment of a skin disorder comprising topically delivering a delivery system comprising a Gemini surfactant in admixture with a biological active agent.

Group III, claim 23, drawn to a method for treatment of a metabolic disease comprising topically delivering a delivery system comprising a Gemini surfactant in admixture with a biological active agent.

The technical feature linking Groups I-III appears to be that they all relate to a topical delivery system comprising a Gemini surfactant in admixture with a biological active agent. It is further noted that the delivery system is at least in the form of a cream, a lotion, a paste, an ointment, a foam, a gel, a lipid formulation, an emulsion, a solution or a suspension (see at least claim 8).

At the effective filing date of the present application (10/03/2003), Camilleri et al (WO 99/29712; IDS) already disclosed at least a mixture of peptide-based Gemini compounds and polynucleotides for gene therapy and genetic immunization in whole organisms as well for transfection of polynucleotides in cells in culture (pages 5-6). In an exemplification, such mixture is in a serum-free solution medium (see at least example 17, page 25, second paragraph), and therefore it would also be suitable for topical delivery. Accordingly, the mixture solution containing peptide-based Gemini compounds and polynucleotides of Camilleri et al falls within the breadth of a topical delivery system as broadly claimed.

Therefore, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter is restricted into the above Groups of Inventions for the following reasons.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

Art Unit: 1633

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the topical delivery system of Group I can be used for treatment of a metabolic disease of Group III.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the topical delivery system of Group I can be used for treatment of a skin disorder of Group II.

Inventions II and III are drawn to different methods having different desired therapeutic end-results. For example, the method of Group II is directed to the treatment of a skin disorder, whereas the method of Group III is drawn to the treatment of a metabolic disease.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a

Art Unit: 1633

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

***Species restriction:***

**A. Should Applicants elect Group I,** this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- 1. (a) anionic gemini surfactant; (b) a gemini cationic surfactant; (c) a neutral gemini surfactant; (d) an amphoteric gemini surfactant; (e) a single specific mixture of (a)-(d).**
- 2. (a) a cream; (b) a lotion; (c) a paste; (d) an ointment; (e) a foam; (f) a gel; (g) a lipid formulation; (h) an emulsion; (i) a solution; and (j) a suspension.**

Art Unit: 1633

**3. (a) DOPE; (b) cholesterol; (c) diethylene glycol monoethyl ether; (d) polyglyceryl 3-diisostearate; (e) PEG-8 caprylic; (f) capric glycerides; and (g) octyldodecyl myristate.**

**B. Should Applicants elect Group II,** this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of a skin disorder are as follows:

**(a) scheroderma, (b) atopic dermatitis; and (c) psoriasis.**

**C. Should Applicants elect Group III,** this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of a metabolic disease are as follows:

**(a) gyrate atrophy; (b) maternal hyperphenylalaninemia; (c) familial hypercholesterolemia; and (d) phenylkeonuria.**

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims



Art Unit: 1633

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the aforementioned species is different structurally and has different properties one from the others, and with respect to skin disorder and/or metabolic disease each of the recited disorder or disease has different symptoms, causes and progression one from the others. Therefore, each different structure or different skin disorder/metabolic disease can be considered to be a “special technical feature”; and therefore the listed species lack the same or corresponding special technical features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Voitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.**

Art Unit: 1633

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/

Primary Examiner, Art Unit 1633